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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/598,327	08/24/2006	**Olivier Gerard**	FR040029US	2707

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PHILIPS INTELLECTUAL PROPERTY & STANDARDS
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EXAMINER	
GUPTA, VANI	
ART UNIT	**PAPER NUMBER**
3768	
MAIL DATE	**DELIVERY MODE**
07/08/2009	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/598,327	GERARD ET AL.	
	Examiner	Art Unit	
	VANI GUPTA	3768	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-10* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-10* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☒ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *04 June 2008* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☒ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *8/24/06*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Specification

The abstract of the disclosure is objected to because the abstract of the disclosure does not commence on a separate sheet in accordance with 37 CFR 1.52(b)(4). A new abstract of the disclosure is required and must be presented on a separate sheet, apart from any other text. Correction is required. See MPEP § 608.01(b).

Inventorship

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re*

Goodman, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

1. ***Claim 1 is provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claim 1 of copending Application No. 10/596,43.***

Although the conflicting claims are not identical, they are not patentably distinct from each other because the claim(s) of the present application includes features that are obvious variants of the features of the conflicting claim(s), as one of ordinary skill in the art would be aware that boarder features of the present claim(s) such "first ultrasound localization," and "second X-ray localization" would encompass the narrower features of the conflicting claim(s), such "first localization of region of interest within ultrasound acquisition means," and "second localization of region of interest within said referential of the X-ray acquisition means."

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

1. ***Claims 1-10 are rejected under 35 U.S.C. 103(a) as being unpatentable over Kusch (US 2002/0018588 A1) in view of Gilbon et al. (US 6,996,430 B1).***

Regarding Claim 1, Kusch discloses a medical imaging system **(*FIGURE*)** comprising

a. an X-ray acquisition means **(*C-arm x-ray apparatus; 1*)** capable of acquiring a two-dimensional X-ray image comprising a projection of said medical instrument in accordance with a geometry of said X-ray acquisition means ([0023 - 0025];

b. an ultrasound acquisition means ***(ultrasound device; 2)*** capable of acquiring a three-dimensional ultrasound data set of medical instrument using an ultrasound probe ***(ultrasound scanner; 24)*** (pgs. [0013], [0022 – 0026]);

c. a means for localizing ***(reference elements of navigation system; 6 and 7)*** said ultrasound probe within a referential of the X-ray acquisition means (pg. [0027 - 0028]);

d. a means for providing a first ultrasound localization of said medical instrument within a referential of said ultrasound acquisition means (***Figure, #7 and 8***; and pg. [0030]). Reference (***8***) capable of being coupled to a "subject" such as a medical device (pg. [0022], second to last sentence);

e. means for converting said first ultrasound localization within said referential of the ultrasound acquisition means into a first X-ray localization within said referential of the X-ray acquisition means, using said localization of the ultrasound probe (pg. [0028]);

f. means for providing a second X-ray localization of said projection of the medical instrument in a referential of said two-dimensional X-ray image (***Figure, #6 and 8***; and pg. [0030]; and rejection of Claim 1(d));

g. means for mapping said three-dimensional ultrasound data set with said two-dimensional X-ray image in accordance with a transformation, which minimizes a distance between a projection of said first X-ray localization on said two-dimensional X-Ray image in accordance with said geometry of the X-ray acquisition means and said second X-ray localization; and means for generating and displaying a bi-modal representation of said medical instrument in which said two-dimensional X-ray image and said mapped three-dimensional ultrasound data set are combined (Figure, 19, 21, 25, 26; and pg. [0029 – 0034]; wherein "calibration" minimizes the distance, or corrects measurements of positions of objects of interest).

However, Kusch differs from claim 1 in that Kusch does not specifically suggest that the "subject" to which reference (8) may be coupled to is a medical instrument to be guided in a patient body.

Nonetheless, Gilbon et al. teaches a "treatment-applying probe" (***fig. 1, 170;*** and col. 7, lines 51 – 60), which may be used by a dual-modality imaging system, comprising ultrasound and tomography imaging capabilities. The probe may be navigated within the body with assistance of the imaging devices (***figs. 1 and 3***; and col. 4, lines 1 – 25).

Accordingly, it would have been prima facie obvious to modify the dual-medical imaging system of Kusch to include the medical device of Gilbon et al., because an "increasing number of medical procedures are performed by navigating a probe within a body," which is accomplished by assistance of fluoroscopic (tomographic) and ultrasound imaging (col. 1, lines 55 – 65). Gilbon et al.'s probe is designed with this in mind (col. 8, line 49 – col. 9, line 20).

Regarding Claim 2, Kusch discloses that means for providing a first ultrasound localization and said means for providing a second X-Ray localization of said medical instrument comprise detection means for detecting localization features of said medical instrument (see rejection of Claim 1(d) and (3).

Regarding Claims 3 – 6 and 8, the limitations refer to features that do not further limit the structure of the present invention. Additionally, Kusch or Kusch in view of Gilbon et al. is capable of performing the functionality of Claim 1, while keeping the present features in mind: (Gilbon et al.: col. 8, lines 29 – 30 and col. 9, lines 41 – 44).

Furthermore, with respect to Claim 5, Applicant should note that means for detecting said localization features that comprise a plurality of landmarks of said medical instrument is an

obvious variant of claims 2 and 3, as it is known in the art to perform the same function multiple times and mere duplication of the essential working parts of a device involves only routine skill in the art. See *in re* St. Regis Paper Co. vs. Bemis Co., 193 USPQ 3, 11 (7th Cir. 1977). ***The same applies to*** transformation comprises a translation and three rotations of ***Claim 6***.

Regarding claims 7 and 9, the limitations refer to features that do not further limit the structure of the present invention, but rather refer to intended use of non-structural (or functional) features of the present invention. Furthermore, Kusch or Kusch in view of Gilbon et al. is not structurally limited from accomplishing the objectives of these claims (see Gilbon et al. for further details —preferred line of sight (PLOS), col. 9 , line 45 – col. 10, line 56).

Regarding Claim 10, for a method of guiding a medical instrument in a patient body, comprising the steps of:

a. acquiring a two-dimensional X-ray image using an X-ray acquisition system, said two- dimensional X-ray image comprising a projection of said medical instrument in accordance with a geometry of said X-ray acquisition system; acquiring a three-dimensional ultrasound data set of said medical instrument using said ultrasound probe; and localizing said ultrasound probe in a referential of said X-ray acquisition system (see Kusch and rejection of Claim 1);

b. providing a first localization of said medical instrument within a referential of said 3D ultrasound data set (see Kusch in view of Gilbon et al. and rejection of Claim 1);

c. converting said first localization within said referential of the 3D ultrasound data set into a first X-Ray localization within said referential of the X-ray acquisition system;

and providing a second localization of said projection of the medical instrument in a referential of the two-dimensional X-Ray image (see Kusch and rejection of Claim 1);

d. mapping said three-dimensional ultrasound data set with said two-dimensional X-ray image in accordance with a transformation, which minimizes a distance between a projection of said first X-Ray localization on said two-dimensional X-Ray image in accordance with said geometry of the X-Ray acquisition means and said second localization (see Kusch: pg. [0030 - 0032] wherein "calibration" minimizes the distance, or corrects measurements of positions of objects of interest).

e. generating and displaying a bimodal representation of said medical instrument in which both 2D X-ray image and said mapped 3D ultrasound data are combined (Kusch – combined images with reference (8) registered with image – pgs. [0030] and [0034]; and Gilbon et al., wherein reference is coupled to medical device and imaging of device itself - col. 7, lines 51 – 52).

Conclusion

The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. ***Buurman (US 5,902,239)*** for image-guided surgery system including a unit for transforming patient positions to image positions.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to VANI GUPTA whose telephone number is (571)270-5042. The examiner can normally be reached on Monday - Friday (8:30 am - 5:30 pm; EST).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Long Le can be reached on 571-272-2083. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/V. G./
Examiner, Art Unit 3768